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Filed : January 4, 2002
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REMARKS

Claim 89 was pending in the subject application. By this Amendment, Applicants amended claim 89.

Support for amended claim 89 can be found, *inter alia*, on page 8, line 1 to page 9, line 9; on page 5, line 17; on page 28, line 27 to page 29, line 3 of the subject application.

Accordingly, Applicants maintain that this Amendment raises no issue of new matter, and respectfully request that this Amendment be entered. Upon entry of this Amendment, claim 89 will be pending and under examination.

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Rejection Under 35 U.S.C. § 112, First Paragraph

In the May 6, 2009 Office Action, the Examiner rejected pending claim 89 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention. To support this assertion, the Examiner cited the decision of the Court of Appeals of the Federal Circuit (hereinafter "the Federal Circuit") in *ARIAAD Pharmaceuticals, Inc. et al. v. Eli Lilly and Company*, 560 F.3d 1366 (Fed. Cir. 2009).

Applicants' Response

Applicants respectfully traverse the rejection for at least the following reasons:

I. ARIAD Decision Has Been Vacated

Applicants note that on August 21, 2009, the Federal Circuit granted ARIAD's petition for rehearing en banc. This decision also vacated and rendered void the earlier ARIAD decision relied upon by the Examiner. The Examiner has been made aware of this fact in a Supplemental Information Disclosure Statement filed September 22, 2009 in connection with the subject application.

In the May 6, 2009 Office Action, the Examiner expressly stated that "the relevant criteria used for determining lack of written description for the '516 patent is appropriate and will be compared to the instant claim 89 and applied.

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accordingly. The instant application fails to meet the criteria set forth by the *Ariad* decision...." Since the *ARIAD* decision relied upon by the Examiner has been vacated, Applicants respectfully submit that the rejection of the pending claim based on the decision has been rendered moot.

II. 35 U.S.C. § 112, Second Paragraph, Does Not Have A Written Description Requirement

Applicants further note that the Federal Circuit granted *ARIAD*'s petition for rehearing to address two issues relevant to the subject application:

- 1) whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement? and
- 2) if a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

Applicants submit the relevant appeal brief and amicus briefs to the U.S. Patent and Trademark Office in a Supplemental Information Disclosure Statement herewith.

Rejection Under 35 U.S.C. § 112, Second Paragraph

In the May 6, 2009 Office Action, the Examiner also rejected pending claim 89 under 35 U.S.C § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In the rejection, the Examiner indicated the following issues:

I. Antecedent Basis

In the rejection, the Examiner alleged that in claim 89 the antecedent basis for "the cell" in the phrase "contacting the cell" is unclear because it is unclear if such antecedent basis is found in the phrase "[a] method for reducing expression in a human cell of a gene", lines 1-2, or instead is found in the term "the plasma membrane of the cell" in line 6-7 or alternatively in the term "the nucleus of the cell" in line 7. The Examiner went on to state that it appears that the antecedent basis for "the cell" in one active method step is referring to the phrase "a human cell" in lines 1-2.

Applicants' Response

Applicants respectfully submit that the language of the pending claim is clear. By this Amendment, Applicants have further amended claim 89 to expressly recite "the human cell", thus making the antecedent basis unambiguously clear.

II. Claim Clearly Pointed Out The "Metes And Bounds" Of The Claimed Invention

The Examiner further alleged that it is unclear how the claim limitations correlate to "the cell" of the active method step. The Examiner asserted that one of ordinary skill in the art would not be able to determine the metes and bounds of

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Applicants invention.

Applicants' Response

Applicants respectfully traverse. First, Applicants note that the Examiner did not provide any factual or legal support for asserting that one of ordinary skill in the art would not be able to determine the metes and bounds of the claimed invention.

Moreover, Applicants respectfully submit that the amendments to claim 89 presented herein fully address the Examiner's rejection. In view of the specification's disclosure, one of ordinary skill in the art would be able to determine the metes and bounds of the claimed invention.

Accordingly, Applicants respectfully submit that the rejection of the pending claim under 35 U.S.C. § 112, second paragraph, should be withdrawn.

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Nonstatutory Obviousness-type Double Patenting Rejection

In the May 6, 2009 Office Action, the Examiner further alleged that the pending claim is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-17, 20-63, 88-176 and 192-203 of U.S. Patent No. 6,410,516. The Examiner noted that Applicants have previously indicated that a Terminal Disclaimer will be filed upon indication of allowable subject matter should the allowable subject matter so require.

Applicants' Response

In response, Applicants hereby maintain that such a Terminal Disclaimer will be filed upon indication of allowable subject matter should the allowable subject matter so require.

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Provisional Nonstatutory Obviousness-type Double Patenting

In the May 6, 2009 Office Action, the Examiner further alleged that the pending claim is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 90 and 91 of copending Application No. 10/037,341.

Applicants' Response

In response, Applicants note that the current rejection is provisional as the cited application is not patented or allowed. Applicants respectfully defer discussion of the provisional rejection until the double patenting rejection is the only rejection remaining in the present application. M.P.E.P. §804(I)(B).

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Supplemental Information Disclosure Statement

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants direct the Examiner's attention to the following disclosures, which are also listed on the attached substitute Form PTO-1449 (**Exhibit A**).

Applicants note that items listed herein are part of a concurrent litigation captioned *ARIAD Pharmaceuticals, Inc., et al. v. Eli Lilly & Co.* involving U.S. Patent No. 6,410,516, which issued from a parent of the subject application.

Applicants further note that items 1-7 were previously submitted to the U.S. Patent and Trademark Office on November 6, 2009 in connection the copending merged reexamination proceeding of U.S. Patent No. 6,410,516, for which the subject application relies on for an earlier effective priority date under 35 U.S.C. §120. In accordance with 37 C.F.R. §1.98(d), copies of items 1-7 are not enclosed herewith but are readily available to the Examiner from the file history of U.S. Patent No. 6,410,516 and its merged proceeding of *Ex Parte Reexamination Control Nos. 90/007,503 and 90/007,828*.

The Examiner is respectfully requested to make the items of record in the subject application by initialing and dating the attached substitute Form PTO-1449, and returning a copy of the initialed and dated form to Applicants' undersigned attorneys.

1. ARIAD's Principal Brief For Plaintiffs-Appellees On Rehearing En Banc, filed October 5, 2009 in the concurrent litigation captioned *ARIAD Pharmaceuticals, Inc., et al. v. Eli Lilly and Company*, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248;

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2. Brief of Amicus Curiae Law Professor Christopher M. Holman In Support Of Neither Party, filed October 13, 2009 in the concurrent litigation captioned *ARIAAD Pharmaceuticals, Inc., et al. v. Eli Lilly and Company*, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248;
3. Brief For Amicus Curiae Roberta J. Morris, ESQ. Ph.D., In Support Of Neither Party, Urging Attention To The Grammatical Structure And Words of 35 USC § 112 ¶ 1, filed October 13, 2009 in the concurrent litigation captioned *ARIAAD Pharmaceuticals, Inc., et al. v. Eli Lilly and Company*, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248;
4. Brief Of Amicus Curiae Novozymes A/S On *En Banc* Rehearing In Support Of Neither Party, filed October 13, 2009 in the concurrent litigation captioned *ARIAAD Pharmaceuticals, Inc., et al. v. Eli Lilly and Company*, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248;
5. Brief Of Amici Curiae Mark D. Janis And Timothy R. Holbrook In Support Of Neither Party, filed October 14, 2009 in the concurrent litigation captioned *ARIAAD Pharmaceuticals, Inc., et al. v. Eli Lilly and Company*, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248;
6. Brief Of Amicus Curiae New York Intellectual Property Law Association On *En Banc* Rehearing In Support Of Neither Party, filed October 15, 2009 in in the concurrent litigation captioned *ARIAAD Pharmaceuticals, Inc., et al.*

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v. Eli Lilly and Company, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248; and

7. Brief Of Amici Curiae The Regents Of The University Of California, Wisconsin Alumni Research Foundation, The University Of Texas System, University Of Rochester, Rensselaer Polytechnic Institute, STC.UNM, The Research Foundation Of State University Of New York, NDSU Research Foundation, And Research Corporation Technologies, Inc. On En Banc Rehearing In Support Of Affirmance Of Judgment, filed October 15, 2009 in the concurrent litigation captioned *ARIAD Pharmaceuticals, Inc., et al. v. Eli Lilly and Company*, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248.

Item 1 is a copy of a Principal Brief filed by ARIAD Pharmaceuticals, Inc. in connection with the en banc rehearing in the concurrent litigation captioned *ARIAD Pharmaceuticals, Inc., et al. v. Eli Lilly and Company*, U.S. Court of Appeals for the Federal Circuit, Docket No. 2008-1248. Items 2-7 are copies of amici briefs filed in the in connection with the same en banc rehearing.

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(c), before the mailing of a Final Office Action. Accordingly, Applicants enclose a check in the amount of ONE HUNDRED AND EIGHTY DOLLARS (\$180.00) for filing this Supplemental Information Disclosure Statement.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorneys invite the Examiner to telephone them at

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the number provided below.

No fee, other than the enclosed \$1110.00 fee for a three-month extension of time and the enclosed \$180.00 fee for filing a Supplemental Information Disclosure Statement, is deemed necessary in connection with filing this Amendment. However, if any fee is required, authorization is hereby given to charge the additional amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Gary J. Gershik

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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EXHIBIT A

of Supplemental Information Disclosure Statement

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